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Title of the Invention

CERVICAL TAPERED DOWEL

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Background of the Invention

Many advances are being made in the field of orthopedic implants, especially in relation to the treatment of diseases, injuries or defects of the spine. For example U.S. Patent No. 5,814,084 ('084 patent) discloses a diaphysial cortical dowel designed for vertebral fusions, which represents a marked improvement over the conventional implants to date. The dowel of the '084 patent is made of bone, thus it is remodeled by the patient and does not suffer from many of the drawbacks observed with metals and synthetics, e.g., inflammation, weakening of surrounding tissues, and antigenicity. The subject invention builds on the successes in this field, by providing an implant that is shaped for implantation at certain locations of the spine and aids in maintaining the proper curvature of the spine as well.

*insert 641*Summary of the Invention.

20 The subject invention relates to an implant made of bone that comprises an elongated body having a first and second ends, wherein the elongated body tapers down its length from a point on or proximate to the first end to the second end or a point proximate thereto. The term "proximate" as used herein is intended to mean a point or region located on the elongated body of the implant that is closer to the end to which it corresponds than the opposing end. For example, proximate to said first end would mean 25 a point or region closer to the first end than the second end. Specifically exemplified is an implant substantially shaped in the form of a dowel.

In a another embodiment, the subject implant has a channel formed therethrough 30 to allow for the disposition therein of osteogenic and other biomedical substances. Optionally, the implant has perforations or holes to facilitate the release and delivery of such substances.

In an alternative embodiment, the subject implant comprises a plurality of sections that can be assembled and secured together. As with the other embodiments described herein, the assembled implant can comprise a channel for the disposition of osteogenic and other substances.

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The subject implant is designed for implantation into the spine during spinal surgeries, especially spinal fusions (arthrodesis). The taper of the subject invention provides an advantage over conventional implants, as it creates the proper support and angulation to maintain the proper curvature of the spine (lordosis). Accordingly, a further embodiment of the subject invention pertains to a method of performing spinal surgery comprising implanting the subject implant into the intervertebral space in a spinal fusion procedure. Further, the novel use of bone as the material for producing the subject implant provides other advantages. Such advantages include the provision of an implant that is remodeled by the body into autogenous bone, and thereby incorporated into the existing bone structure. This leads to a more desirable result with respect to the strength and integrity of the implant. Further, the subject implant does not have the problem of inflammation at the implant site that is often caused by non-remodelable materials, such as metals or plastics. This inflammation can lead to deterioration of the bone surrounding the implant site, which can cause complications and necessitate follow-up surgeries.

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Brief Description of the Drawings

Figure 1 shows side view (Figure 1A) and an end view (Figure 1B) of a starting bone block that is machined to obtain a tapered implant according to the teachings herein, and which comprises holes to engage a securing device.

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Figure 2 shows another embodiment of the subject implant that has a threaded outer surface and comprises a channel that provides a space to dispose biologically active substances. Figure 2A shows a side view of this embodiment and Figure 2B depicts a close-up of the threaded surface.

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Figure 3 shows another embodiment of the subject implant that comprises an oval channel and whose threads are slightly modified compared to the threads shown in Figure 2. Figure 3A shows a side view capturing the channel of the implant. Figure 3B represents a close-up of the threads machined on the exterior of the implant. Figure 3C represents an end-view of this embodiment. Figure 3D shows a side-view of this embodiment that is rotated as to show the side walls of the implant adjacent to the channel.

Figure 4 shows a further embodiment of the subject implant that comprises a wedge-like end to aid in manipulating the implant. Figure 4A shows a side view which depicts the channel and wedge-like end. Figure 4B shows a perspective view of this embodiment. Figure 4C shows an end-view of the wedge-like end. Figure 4D shows a side view that is rotated as to show the side walls of the implant adjacent to the channel.

Figure 5 shows a further embodiment of the subject implant that tapers from one end to the other but has a region in the middle of the implant that is more narrow than either end.

Figure 6 shows a further embodiment of the subject implant that comprises a slot formed on the wider of the two ends. Figure 6A is a perspective view of this embodiment. Figure 6B is a side view of this embodiment. Figure 6C is an end-view of the wider end of this embodiment.

Figure 7 shows an end-view (Figure 7B-C) and side view (Figure 7A) of several drives for securing the subject implant into place.

Figure 8 shows side views (Figures 8A-B) and end view (Figure 8C) of a further embodiment of the subject implant.

Figure 9 shows a further embodiment of the subject implant that comprises pinch cut out for engaging a securing device. Figure 9A is a side view of an embodiment that

has a channel and smooth exterior. Figure 9B is an end view of the embodiment shown in Figure 9A. Figure 9C is a side view of the embodiment of Figure 9A which has a threaded exterior surface.

5 **Figure 10** shows a perspective view of another embodiment of the subject invention that comprises a number of separate pieces (Figure 10A) that are assembled into a single unit (Figure 10B).

10 **Figure 11** shows a perspective view (Figure 11A), an end-view (Figure 11B), a cross-sectional view (Figure 11C), and a side view (Figure 11D) of another embodiment of the subject implant that is perforated to facilitate delivery of biologically active substances.

15 **Figure 12** shows a perspective view (Figure 12A), an end-view (Figure 12B), a cross-sectional view (Figure 12C), and a side-view (Figure 12D) of an embodiment of the subject implant which is a variation of the embodiment shown in Figure 11.

20 **Figure 13** depicts an example of a bone that is an appropriate source for deriving an implant having a wedge-like end.

25 **Figure 14** represents a schematic for procuring a bone block from the bone depicted in Figure 13, which can then be machined to form an implant according to the teachings of the subject invention.

Description of the Preferred Embodiments

Turning now to the drawings, Figure 1A-B show an example of a bone block **100** that is then tapered according to the teachings of the subject invention. The dashed lines
30 **A** depict the tapering of the bone block, which can be accomplished by conventional machining methods, e.g., with a lathe and in particular, a CNC lathe. Holes **105** are

drilled into the bone block via a drill to engage a securing device for positioning of the implant of the subject invention into the spine. Preferably, 4 holes are drilled in a square configuration suitable for engaging a specially adapted securing device having four prongs for insertion into holes **105**. Typically, the subject implant is secured by rotation.

- 5 See Figure 1B. Machining attachment hole **110** is formed in the bone block **100** which provides a means for the block to be positioned in a machine such as a mill or lathe to hold the block steady during machining, to ensure proper alignment, and to permit rotation of the workpiece during machining.

- 10 In Figure 2A-B, there is shown another embodiment **200** of the subject implant. As shown in Figure 1, embodiment **200** comprises holes **205** for engaging a securing and driving device. Further, this embodiment comprises a channel **220** that preferably transverses completely through the implant. Channel **220** provides a space into which an osteogenic material can be disposed to aid in the healing and bone formation process.
- 15 Also, the inventors have discovered that provision of the channel **220** aids in release of bone morphogenetic proteins (BMP) naturally present in the bone used for producing the subject implant and better contact of adjacent vertebrae with the osteogenic material within said dowel. In addition, in embodiments of this invention, channels, pores or the like may be formed, preferably connecting the exterior of the implant with the channel, to
- 20 better induce seepage of growth factors from the osteogenic material in the channel or in the bone into the surrounding tissue. Embodiment **200** also comprises a machining attachment hole **210**. Various dimensions of the implant are noted in Figure 2A-B, represented by the letters **B-G**. The skilled artisan will readily appreciate that these dimensions can be adapted to suit various sized patients, including infants, children, and
- 25 adults. The following values are to be viewed as preferred values. Length **B** can range from about 5 to about 25 mm, and preferably from about 10 to about 15 mm. The root diameter **C** can range from about 3 to about 15 mm, and preferably from about 4 to about 11 mm. The taper angle **D** can range from about 1 to about 8 degrees, and preferably from about 3 to about 5 degrees. **E** can range from about 0.3 mm to about 1mm, and
- 30 preferably from about 0.4 mm to about 0.6 mm. The radius **F** of the thread profile can range from about 0.3 mm to about 1.3 mm, and preferably from about 0.5 mm to about

0.9mm. The pitch **G** of the thread profile can range from about 0.08 to about 2 mm, and preferably from about 1 mm to about 1.8 mm.

In Figure 3A-D, there is shown a further embodiment **300** of the subject implant that is similar to embodiment **200** except that the channel **320** is oval in shape and the thread profile is slightly modified. The oval shape of the channel **320** is achieved by drilling a circular hole through the implant, and then drawing an appropriately dimensioned broach through the circular hole. Preferably, the broach has disposed thereon cutting teeth which change in shape as the diameter of the broach increases from a circular to an oval circumference. Embodiment **300** also comprises a machining attachment hole **310**. Those dimensions noted in Figures 3A-D have similar values to that described above for embodiment **200** unless otherwise indicated. Dimension **H** comprises the length of the channel **320** which can range from about 4 to about 8 mm. It represents the angular relation of the holes **305** from the center axis of the implant. As shown, holes **305** are preferably placed 45 degrees above and below the x-axis. Figure 3B shows the thread profile comprising a ridge **J**, which can range from about 0.05 mm to about 0.15 mm. Further, embodiment **300** comprises a machining attachment hole **310**.

Figure 4A-D, show a further embodiment **400** of the subject implant which comprises oblique sides **415** thereby forming a “roof-top” or wedge-like shape on end **410** of the implant to engage a securing device, wherein the securing device is shaped to conform to end **410**. Embodiment **400** comprises a channel **420**. Further, the dimensions noted in Figure 4A-D have the same values as above, unless otherwise indicated.

Embodiment **400** comprises a substantially planar or flat end **425** having a dimension **L** toward which oblique sides **415** slope and connect. Dimension **L** preferably ranges from 0.5 to about 5 mm. A securing device hole **430** is formed into the wedge end which is designed to engage to a securing device to thereby further stabilize the implant on the securing and driver device during implantation. Dimensions **M** and **N** preferably range from about 0.5 mm to about 7 mm. More preferably, dimension **N** is equal to or larger

than dimension **M**. Wedge angle **P** preferably ranges from about 45 to about 90 degrees, and preferably is set to a standard style angle to match a reciprocal angle on a driver tool.

It is appreciated in the art that human donor tissue is extremely limited in supply.

5 Thus, it is always advantageous to develop methods of maximizing the use of donor tissue. With this goal in mind, it was discovered that the use of the natural architecture of certain bones in the body are suitable for providing a wedged end as described above for embodiment **400**. For example, the tibia comprises an anterior ridge along a substantial portion of its length. It was found that excising block sections along such a ridge can
10 provide oblique sides, thereby avoiding having to machine and discard precious bone material to produce such oblique sides, while preserving donor bone stock for other applications. Where donor bone is less scarce, as in the use of xenograft bone stock, (including but not limited to bovine, ovine, equine, canine or the like) or if allograft bone is in abundant supply, use of the wedge shaped driving structure is less critical. Where
15 used, however, the wedge-shaped driving structure fits conveniently into a complementary driver device for rotation of the implant.

In an alternative embodiment, as shown in Figures 13 and 14, a method of procuring the subject implant comprises obtaining a long bone, such as the tibia **1300**,
20 and cutting off the ends **1310** and **1320** from the elongated central portion (dashed lines **AA**). Figure 14 shows an end-view of the resulting central portion section produced after excision of the end portions **1310** and **1320**. At this point, sections (dashed lines **BB**) along the ridge **1340** of the tibia are excised which comprise a wedge end as a result of the natural architecture of the bone. Those skilled in the art will understand that this
25 method can be applied to other bones in the body having a desired architecture.

In Figure 5, there is shown a further embodiment **500** of the subject implant that tapers from one end to the other but has a region in the middle of the implant **505** that is more narrow than either end. Embodiment **500** also preferably comprises oblique sides
30 **515** and a securing device hole **530**.

In Figure 6A-C, there is shown another embodiment **600** of the subject implant having a slot **635** formed on the wider of the two ends of the implant. The slot **635** is designed to engage a securing and driving device, such as, for example, a flat-head screwdriver. As in other embodiments, embodiment **600** comprises a channel **620** and a
5 securing device hole **630**. Dimensions **B**, **D**, **H**, and **O** shown in Figure 6A-C, have similar values as described above.

In Figure 7A-D, there are shown further embodiments of the subject implant that comprises a peg **705** contiguous with and extending from end **750**, the wider of the two
10 ends of the implant. The peg acts as driver to turn and secure the implant when engaged to a securing device. The peg device may be round for being driven by a collet, or may be square or otherwise shaped for secure torquing by a reciprocal driving means. Figure 7B shows an end-view of the narrower end **755**. Figures 7C and D show various alternatives for the shape of the peg, e.g., square and hexagonal. The skilled artisan will
15 appreciate other appropriate shapes can be used, e.g. octagonal, triagonal, etc. In addition, it will be appreciated that the drive means may be recessed into the implant and driven by an appropriately shaped driver.

In Figure 8A-C, there is shown another embodiment **800** of the subject implant
20 that comprises both a wedge-like end **810** and a raised vertex **805** to further aid in engaging a securing device. Embodiment **800** comprises a securing device hole **830** as well. Figure 8C shows an end-view of embodiment **800** showing the raised vertex **805**, securing device hole **830**, and the oblique sides **815**. The value of **D** is the same as that described above. Preferably, as shown in Figure 8A, the implant comprises a channel
25 **820**.

Figure 9A-C show a further embodiment **900** of the subject invention that comprises two or more pinch cut outs **905** from the edge of the wider of the two ends **950**
of the implant. The pinch cut outs **905** act to engage a securing device for securing the
30 implant in the patient. Figure 9A shows a version of the embodiment **900** that does not have threads disposed on its surface. Figure 9B shows an end-view of the wider end **950**,

which depicts two pinch cut outs **905** positioned on opposing sides of the implant. Figure 9C shows a threaded embodiment. Figure 9D shows an embodiment that comprises a channel **920** and a narrower stepped portion **930** at its wider end **950**.

5 Those skilled in the art will appreciate that the subject implant does not necessarily comprise threads. However, threads are preferred in most cases, as they aid in securing the implant in the patient. Rotation of the subject implant results in the threads digging into the adjacent bones thereby forming a tight contact.

10 In Figure 10A-B, there is shown another embodiment **1000** of the subject implant that is comprised of two or more sections that are assembled into a single unit. Embodiment **1000** comprises a first section **1004** and a second section **1005** that are placed contiguous to each other and then secured together by pins **1010**. The pins **1010** may be formed from any appropriate material, including but not limited to cortical bone,
15 titanium, stainless steel, hydroxyapatite, bioactive glass, polylactic acid and like polymers. The second section has a slot **1015** formed thereon for engaging a securing device, as well as a securing device hole **1030** for further stabilization on the securing device during implantation. Figure 10B shows the embodiment **1000** as assembled. In addition to the slot **1015** and the securing device hole **1030**, Figure 10B illustrates the
20 formation of a channel **1020** when the implant is assembled. Those skilled in the art equipped with the teachings herein will appreciate that the second section **1005** comprising the slot **1015** could be configured to have formed thereon any of the other driver means described herein, e.g., wedge, raised ridge, peg, pinch, 4-pin, etc.

25 Figure 11A shows a perspective view of further embodiment **1100** of the subject implant, having a tapered body resulting in a smaller diameter for the front end **1110**, and a larger diameter for the back end **1120**. The back end **1120** comprises a hex drive **1130** formed therein for insertion and rotation of the implant. Implant **1100** defines a channel **1140** for use of packing biologically active substances. Holes **1150**, which radiate from
30 the channel **1140** to the cortical surface **1160**, allow the biologically active substances to penetrate through the entire implant **1100**. Figure 11B is an end plan view of implant

1100 showing the back end 1120 along with the hex drive 1130. Figure 11C depicts a transverse section of implant 1100 along the AA axis shown in Figure 11B. The hex drive 1130 is shown running from the front end 1110 to the back end 1120. Figure 11D shows a side view of implant 1100, holes 1150, and screw threads 1170 which are inscribed from the front end 1110 to the back end 1120. The screw threads 1170 ease insertion and help to hold the implant in place.

Figures 12A-12D show an alternate embodiment of the cervical tapered dowel depicted in Figures 11A-11D. Figure 12A shows a perspective view of implant 1200, having a tapered body resulting in a smaller diameter for the front end 1210 and a larger diameter for the back end 1220. The back end 1220 contains an instrument hole 1230 along with a score mark 1240 for use with an insertion device to provide torque to the implant. Implant 1200 contains a channel 1250 for packing biologically active substances along with holes 1260 that radiate from the channel 1250 to the cortical surface 1270. Figure 12B is an end plan view of implant 1200 showing back end 1220 along with the instrument hole 1230 and the score mark 1240. Figure 12C depicts a transverse section of implant 1200 along the AA axis shown in Figure 12B. The instrument hole 1230 is shown extending partially through the implant into the channel 1250. Figure 12D shows a side view of implant 1200. The screw threads 1280 ease insertion and help the implant retain its position once implanted.

It will further be appreciated from the present disclosure that the implant may be contacted with cells prior to implantation. For example, bone implants according to this invention may be cultured with stem cells, fibroblasts, muscle cells, neuronal cells or the like or simply contacted therewith or be infused therewith prior to implantation. Preferably, the cells that are contacted with the implant are stem cells, such as those known in the art or which become known hereafter. For example, human mesenchymal or other stem cells, such as those disclosed in any of US Patent Nos. 5,486,359; 5,811,094; 5,197,985; 5,591,625; 5,733,542; 5,736,396; 5,908,784; 5,942,255; 5,906,934; 5,827,735; 5,962,325; 5,902,741; 4,721,096; 4,963,489; (all of which are hereby incorporated by reference), may be contacted with, infused into or cultured on the

implants of the present invention. The plurality of holes in the implant of this invention thus permit for interpenetration of such cells into the interior of the implant prior to implantation, and from the interior of the implant, to assist in remodeling, subsequent to implantation.

5 Alternatively, perforations or holes can be formed in the subject implants, which can control and improve the release and delivery of biologically active substances loaded in the channel, or otherwise infused, embedded or coated on or in the implants. Naturally, the rate of release will be dependent on the size and number of holes provided. As discussed above, the channel of the subject dowels can be packed with various
10 biologically active substances, including, but not limited to, growth factors, antibiotics, nucleic acids, proteins, peptides, antineoplastics, and anti-inflammatory compounds, and the like. Furthermore, the plurality of holes taught herein can facilitate the migration and growth of cells and tissues into the implant. It will be appreciated that any appropriate carrier may be used in association with these biologically active substances, including,
15 but not limited to, gelatin, collagen, mixtures thereof, synthetic compositions, biologically resorbable pastes and the like. Furthermore, the composition may comprise a bone paste composition comprising cortical bone chips, cancellous bone chips, demineralized bone matrix powder (DBM), bioactive glass or other ceramics, growth factors, nucleic acids, proteins, peptides, carbohydrates, lipids and the like. Preferably,
20 the substance packed in the canal is an osteogenic substance and/or comprises tissue regenerating growth factors. See, for example, WO98/40113, herein incorporated by reference. Optionally, or in addition to packing the canal, the subject implants can be infused, soaked and/or coated with various biologically active substances.

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Example: Procedure for Procuring an Implant having a Wedged End from a Human Tibia

Equipment

30 Sherline Mill with 3" vice attached to cross table
Modified Sherline machining lathe with tail stock and tooling bit

Modified Sherline lathe with threading attachment

Core Cutters, 12mm and 14mm

3mm drill bit

#0 starter drill

5 Dial calipers

Fine toothbrush

Scraping tool

Procedure

- 10 An appropriate size cutter was loaded in the chuck of the Sherline mill. The tibia segment was clamped in the vice on the mill table with the anterior of the segment facing up and aligned properly and tightened, and the cutter was aligned to the segment. The motor assembly was adjusted to about 200 RPM, and the cutter was lowered down to the bone and cut through the segment. The cutter was retracted to its original position and
- 15 the cut dowel was removed from the cutter. The foregoing was repeated until all of the dowels were cut.

- To form the wedge end of the dowel, a cut dowel as described above was placed with the anterior end facing the tooling bit in the chuck of the machining lathe and
- 20 tightened. The lathe motor was turned on and the end of the dowel was machined to form 3.5mm oblique side on the end. Using the center drill in the tail-stock, a starter hole was drilled in the end of the dowel. This operation was repeated until all of the dowels were machined with the oblique side and had the starter hole drilled therein.

- 25 The ends of machined dowels opposite the oblique sides were flattened and cancellous bone was removed. To accomplish this, each dowel was individually placed into the chuck with the posterior end of the dowel facing the tooling bit and tightened. The end of the dowel was machined until all the cancellous bone was removed and the dowel was flat. The dowel was then removed from the chuck and measured to determine
- 30 if the length was at a desired length and to determine whether more bone needed to be

removed. Using the center drill in the tail stock, a starter hole in the flattened end of the dowel was drilled. This procedure was repeated for all of the machined dowels.

Next, the 3mm drill bit was secured in the chuck in the tail-stock and tightened. A dowel with the 3.5 mm flat was placed in the chuck facing the drill bit and tightened. The tail-stock was advanced forward until the tip of the drill bit was about 1mm from the end of the dowel and the tail-stock was tightened to the lathe bed. The motor was activated and the drill bit was advanced into the dowel to form a hole 6mm in depth. This procedure was repeated for all of the dowels.

The dowels having the oblique sides, flattened end and holes drilled on both ends were then subjected to the threading lathe. The dowel was placed in the threading lathe and tightened. The air motor was activated with the milling cutter attached and advanced into the dowel until lightly touching the dowel. The threading handle was turned to move the cutter assembly to the right until it cleared the dowel. The cutter was advanced forward to remove the desired amount of bone to achieve the desired dowel diameter. The foregoing procedure was repeated for all of the dowels. Using a burring tool or a scraper, any burrs present were removed from the dowel. A fine tooth brush was used to brush the threads on the dowel to remove any fine burrs.

The teachings of all of the references cited throughout this specification are incorporated herein by this reference to the extent that they are not inconsistent with the teachings herein. Thus, for example, a device made from metal is known for application to the cervical spine (see US Patent 5,782,919; US Patent 5,669,909, herein incorporated by reference for this purpose). The present invention provides an improvement to such devices in that the bone material of the present implant is remodelable, such that autogenous bone replaces implant bone over time to induce a permanent fusion, while metallic implants frequently require removal or cause stress shielding, ultimately causing the implant to fail. It should be understood that the examples and embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and purview of this application and the scope of the appended claims.